

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460



United States  
Environmental Protection  
Agency

Office of Pesticide Programs

Antimicrobials Division (AD)

Tuesday, November 12, 2013

MEMORANDUM

Subject: Acute Toxicity Review for EPA Reg. No.: 3573-OO  
DP Barcode: D413018  
Product Name: Vesta

From: Ian Blackwell, Biologist  
Chemistry and Toxicology Team  
Product Science Branch  
Antimicrobials Division (7510P)

Through: Karen Hicks, Team Leader  
Chemistry and Toxicology Team  
Product Science Branch  
Antimicrobials Division (7510P)

To: Velma Noble, PM 31/ Emilia Oiguenblik  
Regulatory Management Branch  
Antimicrobials Division (7510P)

Applicant: The Procter & Gamble Company

FORMULATION FROM LABEL:

<u>PC Code</u>	<u>Active Ingredient(s):</u>	<u>% by wt.</u>
069149	Didecyl dimethyl ammonium chloride	0.33
	<u>Other Ingredient(s):</u>	<u>99.67</u>
	Total:	100.00

I BACKGROUND: The Procter & Gamble Company has submitted a request to cite acute toxicity data derived from one product to support the data requirements of another product, or, a Similarity Clinic determination. The registrants have had a set of acute toxicity studies conducted on an unregistered product, "Felix II 5X". They later decided not to register that formulation; but, to register a formulation that they consider to be Substantially Similar (to Felix II 5X). The primary eye irritation study was conducted using the EpiOcular Test Method.

II RECOMMENDATIONS:

1. The Chemistry and Toxicology Team (CTT) will allow the Procter & Gamble Company to cite acute toxicity studies conducted on "Felix II 5X" to support "Vesta".
2. Each of the six submitted studies is acceptable.

The acute toxicity profile for File Symbol 3573-OO is currently:

Study	MRID Number	Toxicity Category	Study Status
Acute Oral Toxicity	49081707	IV	Acceptable
Acute Dermal Toxicity	49081708	IV	Acceptable
Acute Inhalation Toxicity	49081709	III	Acceptable
Primary Eye Irritation	49081710	III	Acceptable
Primary Skin Irritation	49081711	III	Acceptable
Dermal Sensitization	49081712	Nonsensitizer	Acceptable

III LABELING: Label Review System

PRODUCT ID #: 003573-00099

PRODUCT NAME: "Vesta"

PRECAUTIONARY STATEMENTS

SIGNAL WORD: CAUTION

## Hazards to Humans and Domestic Animals:

"Harmful if inhaled. Causes moderate eye irritation. Avoid contact with eyes, skin or clothing. Avoid breathing spray mist. Remove and wash contaminated clothing before reuse. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco."

## First Aid:

### If inhaled:

- Move the person to fresh air.
- If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible.
- Call a poison control center or doctor for further treatment advice.

### If on skin:

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

### If in eyes:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
- Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

Label Created by: Ian Blackwell on 11/12/2013    Last Updated by: Ian Blackwell on 11/12/2013

### DATA REVIEW FOR ACUTE ORAL TOXICITY TESTING (§ 81-1, 870.1100)

Product Manager: 31 Reviewer: I. Blackwell

**MRID No.:** 49081707      **Study Completion Date:** 1/29/2003

**Lab Study No.:** 3029.2263

**Testing Laboratory:** Springborn Laboratories, Inc. (SLI)

**Authors:** Dawn D. Rodabaugh, B.S.

**Quality Assurance (40 CFR §160.12):** Included

**Test Material:** SS1080.01; "clear colorless liquid"

**Species:** Hsd: Sprague Dawley SD rat

**Weight:** 229 – 233 g

**Age:** "young adult"

**Source:** Harlan Sprague Dawley, Inc.

### Conclusion:

**1. LD<sub>50</sub> (mg/kg):** Males= Not tested

**Females > 5,000**

Combined= Not tested

**2. The estimated LD<sub>50</sub> is greater than 5,000 mg/kg of body weight.**

**3. Tox. Category:** IV      **Classification:** Acceptable

**Procedure (Deviations from §81-1):**

### Results:

Dosage (mg/kg)	(Number Deaths/Number Tested)		
	Males	Females	Combined
5,000	---	0/3	---

**Observations:** Dark material around nose.

**Gross Necropsy:** No abnormalities.

**DATA REVIEW FOR ACUTE DERMAL TOXICITY TESTING (§81-2, 870.1200)**

**Product Manager:** 31  
**MRID No.:** 49081708

**Reviewer:** I. Blackwell  
**Study Completion Date:** 1/30/0223  
**Lab Study No.:** 3029.2260

**Testing Laboratory:** Springborn Laboratories, Inc.

**Author:** Dawn D. Rodabaugh, B.S.

**Quality Assurance (40 CFR §160.12):** Included

**Test Material:** SS1080.01, "clear colorless liquid"

**Species:** New Zealand White rabbits

**Weight:** 2.4-3.2 kg

**Age:** 12-17 weeks

**Source:** Myrtle's Rabbitry

**Summary:**

1. **LD<sub>50</sub> (mg/kg):**

**Males** > 5,000 mg/kg

**Females** > 5,000 mg/kg

**Combined** > 5,000 mg/kg

2. The estimated LD<sub>50</sub> is greater than 5,000 mg/kg of body weight.

3. **Tox. Category:** IV **Classification:** Acceptable

**Procedure (Deviation From §81-2):** None

**Results:**

**Reported Mortality**

DOSAGE (mg/kg)	(NUMBER DEATHS/NUMBER TESTED)		
	Males	Females	Combined
5,000	0/5	0/5	0/10

**Observations:** Erythema, edema, soft stools, desquamation.

**Gross Necropsy Findings:** Red eye.

## DATA REVIEW FOR ACUTE INHALATION TOXICITY (§81-3, 870.1300)

**Product Manager:** 31      **Reviewer:** I. Blackwell  
**MRID No.:** 49081709      **Study Completion Date:** 3/30/2003  
   **Lab Study No.:** 191-1740

**Testing Laboratory:** MPI Research  
**Author:** Paul E. Newton, PhD, DABT

**Quality Assurance (40 CFR §160.12):** Included

**Test Material:** SS1080.01

**Concentration:** gravimetric = 1.93 mg/L

**Species:** Crl:CD SD (IGS) BR rat

**Weight:** Males= 233.5 – 281.0 g      Females= 174.8-218.5 g

**Age:** 8 weeks

**Source:** Charles River Laboratories

### Summary:

- LC<sub>50</sub> (mg/L)**      **Males** > 1.93 mg/L  
   **Females** > 1.93 mg/L  
   **Combined** > 1.93 mg/L
- The estimated LC<sub>50</sub> is greater than 1.93 mg/L of air.**
- MMAD:** 1.95      **µm**
- Toxicity Category:**      **Classification:**

### Procedure (Deviation From §81-3):

### Results:

#### Reported Mortality

Exposure Concentration	(NUMBER DEATHS/NUMBER TESTED)		
	Males	Females	Combined
1.93 mg/L	1/5	1/5	2/10

Chamber Atmosphere			
Dose Level	MMAD	GSD	particles < $\mu\text{m}$
1.93 mg/L	1.94 $\mu\text{m}$	1.95 $\mu\text{m}$	Not reported

Chamber Environment	
Chamber Volume	63 Liters
Airflow	74 L/min.
Temperature	20-21° C
Relative Humidity	62 - 67%

**Clinical Observations:** Weight loss, difficult breathing, audible breathing, red discharge from nose,

**Gross Necropsy Findings:** Lungs discolored red.

Materials and Methods	
Test Method:	Epithelial <sup>TM</sup> Test Method
Test System:	Epithelial <sup>TM</sup> human cell construct (sterilized human keratinocytes, Matrik Corp.)
Test Protocol:	11/2 No 21/01050
Test Materials:	2 251080/01 (fresh) 2 251080/01 20% dilution
Positive Control:	0.1% Triton X-100
Negative Control:	Sterile deionized water
Test Material:	100 $\mu\text{L}$
Exposure Time:	2, 12, 48 and 96 minutes
pH of Test Material:	
	7.0
	4.5
	6.5

## DATA REVIEW FOR PRIMARY EYE IRRITATION TESTING (§81-4, 870.2400)

### EpiOcular™ Test Method

Product Manager:	31	Reviewer:	Ian Blackwell
MRID No.:	49081710	Study Completion Date:	5/2/2003
EPA File Symbol:	3573-OO	Lab Study No.:	3239

**Study Type:** EpiOcular Assay, in vitro

**Citation:** "Tissue Equivalent Assay with EpiOcular Cultures" by Jill C. Merrill and Massod Rahimi. Institute for *In Vitro* Sciences, Inc. 5/2/2003

**Test Material:** SS1080.01, "clear colorless, non-viscous liquid". The test article was tested neat and as 1 part to four parts sterile water.

**Testing Laboratory:** Institute for *In Vitro* Sciences, Inc. (IIVS)

**Author(s):** Jill C. Merrill and Massod Rahimi

**Quality Assurance (40 CFR §160.12):** The test facility certifies compliance to:

- U.S. EPA GLP Standard (40 CFR §160)
- OECD Principles of Good Laboratory Practice
- Japan (MHLW) GLP Standards
- EC Directive 2004/10/EC, Official Journal of the European Union L50/44

Materials and Methods		
<b>Test Method:</b>	EpiOcular™ Test Method	
<b>Test System:</b>	EpiOcular™ human cell construct (stratified human keratinocyte). MatTek Corp.	
<b>Test Protocol:</b>	IIVS No. SP01050	
<b>Test Material:</b>	1. SS1080.01 (neat) 2. SS1080.01 20% dilution	
<b>Positive Control:</b>	0.3% Triton-X-100	
<b>Negative Control:</b>	Sterile, deionized water	
<b>Test Material Dosage:</b>	100 µL	
<b>Exposure Times:</b>	2, 15, 45 and 90 minutes	
<b>pH of Test Material:</b>		9.0
		4.5
		6.5?

**Summary:**

1. **Toxicity Category:** III

2. **Classification:** Acceptable

**Procedure (Deviations From §81-4):**

- The raw data for the negative control was not included in the report.

**Results:** The positive control fell within two standard deviations of the historical mean.

SS1080.01 100% Concentration (Neat)		
Exposure Time (Minutes)	Percent Viable	T <sub>50</sub>
0.17	91	4.2 min.
1	81.7	
5	42.4	
10	19.5	

SS1080.01 20% Concentration		
Exposure Time (Minutes)	Percent Viable	T <sub>50</sub>
5	86.1	22.1 min.
10	78.8	
30	31.0	
60	17.5	

Positive Control (0.3% Triton X-100)	
Exposure Time (Minutes)	Percent Viable
15	62.9
45	20.8

## DATA REVIEW FOR SKIN IRRITATION TESTING (§81-5, 870.2500)

**Product Manager:** 31

**Reviewer:** I. Blackwell

**MRID No.:** 49081711

**Study Completion Date:** 3/11/2003

**Lab Study No.:** 3029.2261

**Testing Laboratory:** Springborn Laboratories, Inc. (SLI)

**Study Director:** Dawn D. Rodabaugh, B.S.

**Quality Assurance (40 CFR §160.12):** Included

**Test Material:** SS1080.01, "clear colorless liquid"

**Dosage:** 0.5 mL

**Species:** New Zealand White rabbits

**Weight:** 3.3763.570 kg

**Age:** Not reported

**Source:** Myrtle's Rabbitry

### Summary:

1. **Toxicity Category:** III

2. **Classification:** Acceptable

### Procedure (Deviations From §81-5):

**Results:** One hour after exposure, 3/3 test subjects displayed very slight erythema. Twenty-four, 48 and 72 hours after exposure, 3/3 test subjects displayed well-defined erythema. Seven days after exposure, 2/3 displayed well-defined and 1/3 very slight erythema.

**Special Comments:** None

## DATA REVIEW FOR DERMAL SENSITIZATION TESTING (§81-6, 870.2600)

**Product Manager:** 31

**MRID No.:** 49081712

**Reviewer:** I. Blackwell

**Study Completion Date:** 1/27/2003

**Lab Study No.:** 3029.2262

**Testing Laboratory:** Hilltop Lab Animals, Inc.

**Author:** Dawn D. Rodabaugh, B.S.

**Quality Assurance (40 CFR §160.12):** Included

**Test Material:** SS1080.01, "clear colorless liquid"

**Positive Control Material:**  $\alpha$ -Hexylcinnamaldehyde

**Species:** Hartley albino guinea pigs

**Weight:** 375-425 g

**Age:** 6 weeks

**Source:** Hilltop Lab Animals, Inc.

**Method:** Modified Buehler Method

### Summary:

1. **This Product is not a dermal sensitizer.**
2. **Classification:** Acceptable

**Procedure (Deviation From §81-6):** None

**Procedure:** The test subjects were induced with 100% test material once a week for three weeks.

**Results:** No erythema was observed following the first induction treatment. Two (out of twenty) test material-induced animals displayed faint patchy erythema following induction treatment #2. Six (out of twenty) test material-induced animals displayed faint patchy erythema following induction treatment #3. No erythema or edema were reported following challenge.